

meets the requirements for certification at § 486.303. CMS may also terminate an agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. CMS will de-certify the OPO as of the effective date of the involuntary termination.

(c) *Non-renewal of agreement.* CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the requirements for certification at § 486.318, based on findings from the most recent re-certification cycle, or the other requirements for certification at § 486.303. CMS will de-certify the OPO as of the ending date of the agreement.

(d) *Notice to OPO.* Except in cases of urgent need, CMS gives written notice of de-certification to an OPO at least 90 days before the effective date of the de-certification. In cases of urgent need, CMS gives written notice of de-certification to an OPO at least 3 calendar days prior to the effective date of the de-certification. The notice of de-certification states the reasons for de-certification and the effective date.

(e) *Public notice.* Once CMS approves the date for a voluntary termination, the OPO must provide prompt public notice of the date of de-certification and such other information as CMS may require through publication in local newspapers in the service area. In the case of involuntary termination or non-renewal of an agreement, CMS provides public notice of the date of de-certification through publication in local newspapers in the service area. No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the effective date of de-certification.

§ 486.314 Appeals.

If an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive and procedural grounds.

(a) *Notice of initial determination.* CMS mails notice to the OPO of an initial de-certification determination. The notice contains the reasons for the determination, the effect of the determina-

tion, and the OPO's right to seek reconsideration.

(b) *Reconsideration.* (1) Filing request. If the OPO is dissatisfied with the de-certification determination, it has 15 business days from receipt of the notice of de-certification to seek reconsideration from CMS. The request for reconsideration must state the issues or findings of fact with which the OPO disagrees and the reasons for disagreement.

(2) An OPO must seek reconsideration before it is entitled to seek a hearing before a hearing officer. If an OPO does not request reconsideration or its request is not made timely, the OPO has no right to further administrative review.

(3) *Reconsideration determination.* CMS makes a written reconsidered determination within 10 business days of receipt of the request for reconsideration, affirming, reversing, or modifying the initial determination and the findings on which it was based. CMS augments the administrative record to include any additional materials submitted by the OPO, and a copy of the reconsideration decision and sends the supplemented administrative record to the CMS hearing officer.

(c) *Request for hearing.* An OPO dissatisfied with the CMS reconsideration decision, must file a request for a hearing before a CMS hearing officer within 40 business days of receipt of the notice of the reconsideration determination. If an OPO does not request a hearing or its request is not received timely, the OPO has no right to further administrative review.

(d) *Administrative record.* The hearing officer sends the administrative record to both parties within 10 business days of receipt of the request for a hearing.

(1) The administrative record consists of, but is not limited to, the following:

(i) Factual findings from the survey(s) on the OPO conditions for coverage.

(ii) Data from the outcome measures.

(iii) Rankings of OPOs based on the outcome data.

(iv) Correspondence between CMS and the affected OPO.

(2) The administrative record will not include any privileged information.

(e) *Pre-Hearing conference.* At any time before the hearing, the CMS hearing officer may call a pre-hearing conference if he or she believes that a conference would more clearly define the issues. At the pre-hearing conference, the hearing officer may establish the briefing schedule, sets the hearing date, and addresses other administrative matters. The hearing officer will issue an order reflecting the results of the pre-hearing conference.

(f) *Date of hearing.* The hearing officer sets a date for the hearing that is no more than 60 calendar days following the receipt of the request for a hearing.

(g) *Conduct of hearing.* (1) The hearing is open to both parties, CMS and the OPO.

(2) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(3) The hearing officer provides the parties with an opportunity to enter an objection to the inclusion of any document. The hearing officer will consider the objection and will rule on the document's admissibility.

(4) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(5) The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

(6) The hearing officer rules on motions and other procedural items.

(7) The hearing officer regulates the course of the hearing and conduct of counsel.

(8) The hearing officer may examine witnesses.

(9) The hearing officer takes any action authorized by the rules in this subpart.

(h) *Parties' rights.* CMS and the OPO may:

(1) Appear by counsel or other authorized representative, in all hearing proceedings.

(2) Participate in any pre-hearing conference held by the hearing officer.

(3) Agree to stipulations as to facts which will be made a part of the record.

(4) Make opening statements at the hearing.

(5) Present relevant evidence on the issues at the hearing.

(6) Present witnesses, who then must be available for cross-examination, and cross-examine witnesses presented by the other party.

(7) Present oral arguments at the hearing.

(i) *Hearing officer's decision.* The hearing officer renders a decision on the appeal of the notice of de-certification within 20 business days of the hearing.

(1) *Reversal of de-certification.* If the hearing officer reverses CMS' determination to de-certify an OPO in a case involving the involuntary termination of the OPO's agreement, CMS will not terminate the OPO's agreement and will not de-certify the OPO.

(2) *De-certification is upheld.* If the de-certification determination is upheld by the hearing officer, the OPO is de-certified and it has no further administrative appeal rights.

(j) *Extension of agreement.* If there is insufficient time prior to expiration of an agreement with CMS to allow for competition of the service area and, if necessary, transition of the service area to a successor OPO, CMS may choose to extend the OPO's agreement with CMS.

(k) *Effects of de-certification.* Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes on or after the effective date of de-certification. CMS will then open the de-certified OPO's service area for competition as set forth in § 486.316(c).

§ 486.316 Re-certification and competition processes.

(a) *Re-Certification of OPOs.* An OPO is re-certified for an additional 4 years and its service area is not opened for competition when the OPO:

(1) Meets two out of the three outcome measures requirements at § 486.318; and

(2) Has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the